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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/955,644	09/18/2001	Eric Silverberg	1893	1184

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EXAMINER

GHALI, ISIS A D

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 12/18/2002

5

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/955,644

Applicant(s)

SILVERBERG ET AL.

Examiner

Isis Ghali

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 September 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☒ Claim(s) 1-14 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' declaration and fee, filed 01/03/2002; and IDS, filed 5/10/2002.

Specification

1. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1-17 of U.S. Patent No.

6,077,527. Although the conflicting claims are not identical, they are not patentably distinct from each other because both of the instant application and the issued patent claim an adhesive composition comprising alkyl acrylate monomer and/or alkyl methacrylate monomer and nitrogen containing monomer.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of an application filed in the United State only if the international application designating the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-6, 8-14 are rejected under 35 U.S.C. 102(e) as being anticipated by PG PUB 2002/0150613 ('613).

PG PUB '613 disclosed a transdermal drug delivery device comprising backing layer, release liner, and adhesive layer comprising the drug (abstract; page 2, 0018; page 10, 0079). The adhesive comprises: (a) 40-90% by weight of alkyl acrylate including n-butyl acrylate and 2-ethylhexyl acrylate, and (b) 15-30% by weight of monomer selected from (meth)acrylamide, N-butyl-acrylamide, or (meth)acrylonitrile (page 3, 0024, 0027; page 5, 0039, 0045; page 6, 0046). The T_g is inherent for particular composition.

6. Claims 1-6, 8-14 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,132,760 ('760).

US '760 disclosed a transdermal drug delivery device including an adhesive layer contains active agent; backing layer, and release liner (abstract; col.5, lines 17-19, 41). The adhesive layer comprises copolymer of: (a) 45-95% by weight of alkyl acrylate including n-butyl acrylate and 2-ethylhexyl acrylate, and methacrylate, and (b) 5-55% by weight of substituted acrylamide, acrylonitrile, methacrylonitrile, and vinyl acetamide (col.2, lines 54-65; col.3, lines 1-28). The Tg is inherent for particular composition.

7. Claims 1-11, 14 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,077,527 ('527).

US '527 disclosed a pressure sensitive adhesive composition for use in transdermal drug delivery devices comprising at least 40% by weight of alkyl acrylate including n-butyl and 2-ethylhexyl acrylate, and 10-60% by weight of substituted acrylamide or methacrylamide including t-octyl acrylamide (abstract; col.2, lines 45-60; col.3, lines 60-67; col.4, lines 8-16). The Tg is inherent for particular composition.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of PG PUB '613, US '760 or US '527.

The teachings of the references are discussed above. However, BGPUB '613 and US '760 do not teach the species of the acrylamide, i.e. t-octyl acrylamide, and US '527 does not teach the backing layer and the release liner of the transdermal device.

It is within the skill in the art to replace one species by another or genus by species known to perform the same function. Thus, it is obvious to replace the substituted acrylamide of any of PG PUB '613 or US '760 by t-octyl acrylamide. In any event, no criticality has been shown in using t-octyl acrylamide in particular.

It is also within the skill in the art to deliver a conventional transdermal drug delivery device comprising backing layer and release liner enclosing the adhesive layer containing the drug.

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to deliver a transdermal drug delivery devices comprising a backing layer, a release liner and an adhesive composition comprising alkyl acrylate and substituted (meth)acrylamide and select the species suitable for the adhesive layer with reasonable expectation of the device to deliver therapeutically active agents transdermally with success.

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6,239,228 disclosed transdermal drug delivery device comprising adhesive layer comprising alkyl acrylate and substituted acrylamide.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (703) 305-4048. The examiner can normally be reached on Monday through Thursday from 7:00 AM to 5:30 PM, Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached on (703) 308-2927. The fax phone

number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Isis Ghali
Examiner
Art Unit 1615



CARLOS AZPURU
PRIMARY EXAMINER
GROUP 1500